NASA Procedural Requirements

COMPLIANCE IS MANDATORY

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Subject: Protection of Human Research Subjects

Responsible Office: Office of the Chief Health & Medical Officer

CHAPTER 2. NASA Institutional Review Boards (IRB)

2.1 IRB Authority

2.1.1 The IRB has authority to approve, disapprove, or require changes in the proposed research protocols and procedures involving human subjects covered by this NPG. Another authority cannot overturn a decision of disapproval; however, a decision of ANO, Center Director, or their designee may change a decision of approval to disapproval.

The IRB may conditionally approve a protocol or recommend changes to disapproved protocols that could result in protocol approval. Any changes must be approved by the IRB prior to initiation or continuation of the protocol. The IRB has the authority to suspend or terminate its approval of research activities that are not being conducted in accordance with the approved protocol, or the policies set forth in this NPG, or that have been associated with serious harm to human subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be promptly reported to the PI, the NASA Center Director, and the ANO. If an IRB disapproves, suspends, terminates, or conditionally approves a research activity, the PI shall be given the opportunity to respond to the decision by either meeting with the IRB or through written correspondence with the Chairperson of the IRB.

2.1.2 When a NASA Center funds research involving human subjects not involving NASA facilities, personnel or equipment, the Center IRB may evaluate such proposals prior to their funding, or the NASA IRB may accept IRB certification for the research proposal from a DHHS OHRP approved non-NASA IRB.

2.2 IRB Responsibility

The primary responsibility of the IRB is to protect the rights and ensure the safety of every person who is a research subject in any NASA facility, including NASA aircraft or spacecraft. This applies to subjects involved in any research conducted or supported by NASA.

2.3 IRB Functions

2.3.1 The IRB reviews all proposals for NASA-conducted or -sponsored, ground-based, aeronautical, and space flight research, that apply to human subjects (the latter applies to the NASA Flight IRB (NFI) only chapter 6), prior to funding, approval, or execution of research. Except when an expedited review procedure is used, this review of proposed research shall be held only at convened meetings at which a majority of the members of the IRB are present including at least one member whose primary concerns are in a nonscientific area. For the research to be approved by the IRB, it must receive the approval of a majority of those members present at the meeting. If human subjects are to participate in multiple research protocols at the same time, the IRB shall review all the research proposals as an integrated protocol to assess the risks and benefits to the research subject.

2.3.2 The IRB conducts a continuing review of research involving humans at intervals appropriate to the degree of risk, but not less than once per year. This continuing review shall include the informed consent particulars, the adequacy of safety precautions taken to date, and a determination as to whether or not proper and comprehensive

information was given to the subject during the process. The IRB shall review all adverse events (whether expected or not), which occur during the conduct of research. In all cases in which there has been an adverse incident reported to the IRB, the IRB must notify the appropriate NASA safety and legal representatives, the ANO, and if appropriate other AA's.

2.3.3 The IRB defines for each approved experiment the extent to which the actual consent process and/or the conduct of the research shall be monitored. If monitoring is deemed necessary, this may be accomplished by appointment of a monitor with specified responsibilities or direct monitoring by selected members of the IRB.

2.3.4 The IRB maintains documentation of IRB activities as prescribed in chapter 6 of this NPR.

2.3.5 The appropriate NASA IRB must review and monitor non-NASA research using NASA facilities, equipment, or personnel involving human subjects.

2.3.6 The appropriate NASA IRB shall review human-used, ground-based simulators. The IRB shall determine the potential risks of the simulator operations to the research subjects. The IRB may then determine that all or some of the operations in the simulator may be IRB exempt, requires expedited review or requires full IRB review.

2.3.7 The ANO or designee will be responsible for developing and administering a NASA Human Protection Training program that is congruent with requirements for Federal funding by DHHS. This or similar training will be mandatory for all NASA IRB members and investigators using human subjects receiving NASA funds or involved in NASA-sponsored research.

2.3.8 The NASA Center IRB overseeing any human subject research for units responsible to that Center shall be responsible for appropriate oversight.

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